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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., SANDOZ INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	Civil Action No. 11-3962 (MLC)(DEA) Civil Action No. 11-5579 (MLC)(DEA) Civil Action No. 13-5815 (MLC)(DEA) (consolidated) Hon. Mary L. Cooper, U.S.D.J. Hon. Douglas E. Arpert, U.S.M.J.

DEFENDANTS' OPENING CLAIM CONSTRUCTION
BRIEF FOR U.S. PATENT NO. 8,598,219

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Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva"), Defendant Sandoz Inc. ("Sandoz"), and Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") (all collectively, "Defendants") respectfully submit this Opening Claim Construction Brief pursuant to the schedule set forth in the Court's May 29, 2014 Joint Stipulation and Order Consolidating Civil Action No. 13-5815 with Civil Action Nos. 11-3962 and 11-5579 [Dkt. No. 174] ("Consolidation Order").

INTRODUCTION

Pursuant to the Consolidation Order, this patent litigation now involves four asserted patents: U.S. Patent Nos. 7,947,724 ("the '724 patent"), 7,947,725 ("the '725 patent"), and 7,960,424 ("the '424 patent") from the "first" action, and U.S. Patent No. 8,598,219 ("the '219 patent") from the "second" action (collectively, the "asserted patents"). The claims of the asserted patents are all directed to ***palonosetron formulations with improved stability***. The Court held a *Markman* hearing in the first action with respect to the claim term "pharmaceutically stable" that is recited in the asserted claims of the '724, '725, and '424 patents, and concluded that expert testimony was required in order to determine the plain and ordinary meaning of that term.

Now, Plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively, "Helsinn" or "Plaintiffs") are asserting claims 1, 2, 6, and 7 of the '219 patent (the "asserted '219 claims") against Defendants.[1] The only disputed claim language appears in the ***preamble*** of independent claim 1 of the '219 patent: "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" (hereinafter, the "disputed

[1] Claim 7 is not asserted against the DRL Defendants.

preamble language"). Unlike the *Markman* proceedings in the first action, the current dispute before the Court — about the preamble — is resolvable without expert testimony.[2]

All of the disputed language is found entirely in the preamble of claim 1. Based on Federal Circuit precedent that "[g]enerally, the preamble does not limit the claims," the disputed preamble language in this case does not limit the asserted '219 claims. *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002). The asserted '219 claims "define[] a structurally complete invention [a palonosetron formulation] in the body of the claims and use[] the disputed preamble language only to state a purpose or intended use for the invention, [viz., for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting]." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Moreover, no exceptions apply here to the general rule that preambles are not limiting because, *inter alia*, there is nothing in the disputed preamble language that "recites essential structure or steps or. . . is necessary to give life, meaning, and vitality" to any of the asserted claims. *Id.* (internal quotations omitted). Accordingly, Defendants respectfully request that the Court find that the disputed preamble language is not a limitation of the asserted '219 claims.

I. FACTUAL BACKGROUND ON THE '219 PATENT

Like the asserted patents in the first action, the '219 patent discloses and claims pharmaceutical formulations of palonosetron, a drug that belongs to a class of antiemetic drugs commonly known as 5-HT_3 (5-hydroxytryptamine) receptor antagonists and that itself was

[2] The parties have likewise agreed that expert testimony is not anticipated at the claim construction hearing. June 9, 2014 Joint Claim Construction and Prehearing Statement at Section V [Dkt. No. 175].

known to be effective for treating emesis.[3] Ex. 1, '219 patent at col. 1, ll. 15-31.[4] Other 5-HT_3 receptor antagonists that were known and/or marketed prior to palonosetron include ondansetron, granisetron, tropisetron, and dolasetron, all of which were administered intravenously to control the emetic effects caused by chemotherapy. *Id.* Intravenous formulations of palonosetron were also known in the prior art, having been disclosed in U.S. Patent No. 5,202,333 to Berger *et al.* ("the '333 patent"). *Id.* at col. 1, ll. 43-54.

The '219 patent purports to address the same alleged problem as the patents in the first action, namely the "***need for a palonosetron formulation with increased stability and thereby increased shelf life***." *Id.* at col. 2, ll. 33-38 (emphasis added). While the '219 patent describes how to make certain stable formulations of palonosetron, the patent specification does not describe how these particular formulations could be used to effectively treat patients with emesis, or specifically to treat patients suffering from cancer chemotherapy-induced nausea and vomiting ("CINV"). In fact, the specification of the '219 patent is completely devoid of clinical trial data or any other disclosure that would indicate what an effective dose of palonosetron would be for reducing the likelihood of CINV in human patients. At most, the '219 patent admits upfront in the Background of the Invention section that one known purpose and intended use of palonosetron was as a potent antiemetic compound for reducing CINV. *Id.* at col. 1, ll. 43-49.

[3] Also like the asserted patents in the first action, the '219 patent claims priority to U.S. Provisional Application No. 60/444,351, which was filed in January 2003. The application for the '219 patent was filed as one of a series of continuation patent applications on May 23, 2013 as U.S. Application No. 13/901,437 ("the '437 application). (S*ee* Ex. 1, '219 patent at cover.)

[4] "Ex. __" refers to the exhibits annexed to the Declaration of Brendan F. Barker filed in support of this brief.

II. LEGAL PRINCIPLES FOR CLAIM CONSTRUCTION

Claim construction is a pure question of law. *Markman v. Westview Instruments Inc.*, 52 F.3d 967, 970-71, 978 (Fed. Cir. 1995) (*en banc*); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (*en banc*). In *Phillips v. AWH Corp.*, the Federal Circuit confirmed that claim terms should be given "their ordinary and customary meaning;" that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*).

The Federal Circuit has stressed the importance of the intrinsic record – the claim language, the specification, and the prosecution history – when construing claim terms. *Id.* at 1317. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Under *Phillips* and its progeny, the patentee "is not entitled to a claim construction divorced from the context of the written description and prosecution history." *Nystrom v. Trex Co., Inc.*, 424 F.3d 1136, 1144-45 (Fed. Cir. 2005). The intrinsic evidence, therefore, controls the claim construction inquiry.

Claim construction begins by looking at the claim language itself. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) ("[t]he starting point for any claim construction must be the claims themselves"). Along with the claims, the specification tends to provide "dispositive" guidance because "it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. Also, "like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1316.

The preamble of a claim generally does not limit the scope of the claim. *See Catalina Mktg.*, 289 F.3d at 808; *see also Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010); *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1295 (Fed. Cir. 2004); *Allen Eng'g*, 299

F.3d at 1346. Pointedly, the Federal Circuit has explained that a preamble is not limiting "where a patentee ***defines a structurally complete invention in the claim body*** and ***uses the preamble only to state a purpose or intended use for the invention.***" *Catalina Mktg.*, 289 F.3d at 808 (emphasis added) (internal citations omitted). "[P]reambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure. . . . [S]tatements of intended use or asserted benefits in the preamble may, in rare instances, limit apparatus claims, but only if the applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art." *Id.* at 809 (citing *In re Gardiner*, 171 F.2d 313, 315-16 (C.C.P.A. 1948)). A preamble may also limit the invention if it "recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim," or where "dependence on a particular disputed preamble phrase for antecedent basis. . . indicates a reliance on both the preamble and claim body to define the claimed invention." *Id.* at 808.

III. ARGUMENT

A. The Disputed Constructions

The chart below sets forth Defendants' understanding of the claim construction positions presented by the parties to the Court for adjudication:

Disputed Preamble Language	Defendants' Construction	Plaintiffs' Construction
"for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting"	Not a limitation of the asserted '219 claims, so does not need to be construed.	Limiting on the asserted '219 claims and should be given its plain meaning.

B. The Disputed Preamble Language Of The Asserted '219 Claims Is Not A Claim Limitation

Claim 1 of the '219 patent recites:

> A pharmaceutical single-use, unit-dose formulation ***for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting***, comprising
> a 5 mL sterile aqueous isotonic solution, said solution comprising:
> palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;
> from 0.005 mg/mL to 1.0 mg/mL EDTA; and
> from 10 mg/mL to 80 mg/mL mannitol,
> wherein said formulation is stable at 24 months when stored at room temperature.

Ex. 1, '219 patent at col. 10, ll. 2-12 (emphasis added). The disputed language that is before the Court for construction is the portion of the preamble of claim 1 that recites "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." Claims 2, 6, and 7 all depend from claim 1, and thus under 35 U.S.C. § 112(d) these dependent claims only "incorporate by reference" the disputed preamble language if that language is found to be a limitation of claim 1. 35 U.S.C. § 112(d) (2014). Defendants' position is that the disputed preamble language of claim 1 is not a claim limitation and therefore does not need to be construed or incorporated by reference into the dependent claims.

Consistent with the Federal Circuit's general rule that preambles do not limit claims, the disputed preamble language of claim 1 is not a limitation. *See Catalina Mktg.*, 289 F.3d at 808; *Am. Med. Sys.*, 618 F.3d at 1358. Although the Federal Circuit has set forth exceptions to this general rule, none of them applies here. *See Catalina Mktg.*, 289 F.3d at 808-09. For example, the disputed preamble language neither recites "essential structure or steps" nor is "necessary to give life, meaning, and vitality" to the claim. The body of claim 1 "defines a structurally complete invention" — it purports to include all of the limitations necessary to make a formulation of palonosetron hydrochloride that is stable as claimed — and nothing about the

intended use "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" is an essential structure, or gives life, meaning, and vitality to the claim. *See id.* at 808-09; *see also Am. Med. Sys.*, 618 F.3d at 1359-60 (preamble is not a limitation where "the bodies of the asserted method claims contain all the steps necessary to practice the invention"); *Marrin v. Griffin*, 599 F.3d 1290, 1294 (Fed. Cir. 2010) (preamble is not a limitation where "preamble language only added an intended use"). Importantly, the same principals hold true for dependent claims 2, 6, and 7 of the '219 patent — the additional limitations recited in these dependent claims, compared to claim 1, are all structural limitations. In fact, if the disputed preamble language were deleted, the claimed formulations of the '219 patent would not change. *See Intirtool*, 369 F.3d at 1295 (if the body of the claim "describes a structurally complete invention such that the deletion of the preamble phrase does not affect the structure or steps of the claimed invention . . . the preamble is generally not limiting") (internal quotations and citations omitted); *see also Catalina Mktg.*, 289 F.3d at 809. Here, the disputed preamble language only "state[s] a purpose or intended use for the invention," and therefore under *Catalina Mktg.*, the preamble is not limiting. *Id.* at 808.

Consequently, the disputed preamble language may "give context for what is being described in the body of the claim." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1287-89 (Fed. Cir. 2008) (finding the "as it is being transferred" language, which was added to the preamble during prosecution, provided context for the asserted claim but was not limiting). Nevertheless, the disputed preamble language only "state[s] a purpose or intended use for the invention." *Catalina Mktg.*, 289 F.3d at 808. Under *Catalina Mktg.* and other Federal Circuit precedents, such preamble language is not limiting. *Id.*; *see also Intirtool*, 369 F.3d at

1294-96; *Allen Eng'g*, 299 F.3d at 1346-47; *Marrin*, 599 F.3d at 1294; *Symantec*, 522 F.3d at 1288.

Moreover, no claim terms in the body of claim 1 depend on the disputed preamble language — "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" — for antecedent basis. *Catalina Mktg.*, 289 F.3d at 808; *Am. Med. Sys.*, 618 F.3d at 1359 (claim's preamble did not provide antecedent basis, and thus was not a limitation, where it did not provide "context essential to understanding the meaning of any of the terms in the body"). This is evident from the claim language itself: there are no words in the body of claim 1 that refer back to any word in the disputed preamble language. Therefore, the "antecedent basis" exception likewise does not apply here to render the disputed preamble language a limitation of claim 1.[5]

Finally, there is also no evidence of "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *Catalina Mktg.*, 289 F.3d at 808. The patentees never relied upon the disputed preamble language to distinguish any prior art during prosecution of the '219 patent. Instead, the prior art cited by the examiner, and distinguished by the patentees, related solely to the claimed excipient and concentration limitations recited in the body of claim 1.[6] Thus, the "distinguishing prior art" exception is also not applicable here. *See Symantec*, 522 F.3d at 1289 (preamble is not a claim limitation where the prosecution history "fail[ed] to demonstrate 'clear reliance on the preamble during prosecution to distinguish the

[5] By contrast, the portion of the preamble that recites a "pharmaceutical single-use, unit-dose formulation" provides an antecedent basis for the "said formulation is stable. . ." limitation recited in the body of claim 1. Accordingly, the parties do not dispute that this portion of the preamble limits the asserted '219 claims and should be given its plain and ordinary meaning.

[6] *See, e.g.*, Ex. 2, 7/29/13 Office Action; Ex. 3, 7/30/13 Amendment and Response.

claimed invention from the prior art'") (quoting *Catalina*, 289 F.3d at 808); s*ee also Marrin*, 599 F.3d at 1294; *Intirtool*, 369 F.3d at 1295.

In sum, the Federal Circuit's default principle holds: the disputed preamble language, which expresses only an intended use of the claimed formulations, does not limit the asserted '219 claims.

CONCLUSION

For all of the reasons set forth above, Defendants respectfully request that the Court find that the disputed preamble language, "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting," is not a limitation of asserted claims 1, 2, 6, and 7 of the '219 patent.

Dated: June 19, 2014

Respectfully,

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CERTIFICATE OF SERVICE

I, Mayra V. Tarantino, hereby certify that on June 19, 2014, I caused a copy of the Defendants' OPENING CLAIM CONSTRUCTION BRIEF FOR U.S. PATENT NO. 8,598,219 and the DECLARATION OF BRENDAN F. BARKER IN SUPPORT OF DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF to be served on counsel for Plaintiffs' through the Court's ECF system and by email.

By: *s/Mayra V. Tarantino*